

### **REMARKS**

Claims 1-4, 7, 8, 11, 14, 17, 20-22, 27, 34 and 36 (and presumably claim 5) are pending. Claim 6 is withdrawn. Claims 9, 10, 12, 13, 15, 16, 18, 19, 23-26, 28-33, 35, and 37-40 are canceled. Claim 7 has been amended to eliminate dependency from multiple dependent claim 3. Reconsideration of the application is requested.

### **Information Disclosure Statement**

Reference A1 (US244229) listed on the IDS submitted on 10/1/2007 claims priority from Reference B1 (CN 1032337), and being cumulative need not be considered.

Attached is a corrected Form PTO-1449 with includes dates for references C4 and C12 cited on 8/23/2006. It is requested that the Examiner consider them and initial the Form PTO-1449, and return it to the undersigned attorney.

### **35 USC 103**

All of the pending claims 1-4, 7, 8, 11, 14, 17, 20-22, 27, 34 and 36 (and presumably claim 5) were rejected as being obvious over Hedenstrom et al. (2002/0058674) and Mitra et al. (WO/2002/102377) in further view of Gordon et al. (20040014779). Applicants respectfully traverse.

While the '674 discloses delivery using some of the same devices, it does not disclose or suggest using the devices in such a way as to fall within the present claims. Claim 1 requires ". . . **removing from the mucosal surface a substantial amount of the IRM** . . . ." This would not normally happen using a suppository, direct cervical applicator, or cervical cap because a drug formulation is normally released from such devices before they are removed. In other words, unless intentionally designed to remove the drug formulation along *with* the device, e.g., by having the IRM drug adhered to the device so it does not get easily separated, the IRM drug formulation will normally be released from the device and not removed from the mucosal surface when the device is removed. That is usually the intent.

The present claims thus differ importantly from the cited art because they require that the IRM be placed in contact with the mucosal surface but then be removed from such contact. This is important because it has been found that IRMs can strongly "kick-start" the immune response

after relatively short contact, and be removed to avoid unwanted side-effects of prolonged exposure. This is not disclosed by the '674.

Without knowing that the IRM drug compounds can (a) activate or “jump-start” an effective immune response with a relatively short duration of contact, and (b) that removing contact of the IRM drug compound can lessen unwanted side effects even though the immune response has been sufficiently activated, there is no reason one skilled in the art would have been motivated to practice the claimed interrupted delivery method of the invention. Nor would there have been any reasonable basis to expect success. So the mere disclosure of some of the same devices in the '674 (in combination with other cited references) could not have rendered the present claims obvious.

In view of the above, it is submitted that a *prima facie* case of obvious has not been established and the application is in condition for allowance.

Examination and reconsideration of the application is requested.

Respectfully submitted,

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Date

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